

Clinical Edit Criteria Proposal

Drug/Drug Synagis[®] (palivizumab)
 Class:
 Prepared for: Missouri Medicaid
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☒ New Criteria

☐ Revision of Existing Criteria

Executive Summary

Purpose: Promote prudent prescribing of Synagis[®] (palivizumab).

Why was this Issue Selected:

In November of 1998, the American Academy of Pediatrics (AAP) published guidelines for the use of palivizumab. Only pediatric patients at high risk for RSV infection require prophylaxis with this agent. Because the associated costs of palivizumab may be as high as \$5,000 per patient per season, prudent prescribing of this agent is imperative.

Program-specific information:

Drug	Claims	Expense
• Synagis [®] (palivizumab)	4,438	\$3,478,789

Setting & Population: All individuals prescribed palivizumab.

Type of Criteria:

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/> Dose Optimization

Data Sources: ☐ Only administrative databases ☒ Databases + Prescriber-supplied

Purpose of PA Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payers are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Prior authorization criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Prior authorization criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why Has This Clinical Issue Been Selected For Review?

In the United States, respiratory syncytial virus (RSV) infection accounts for more than 90,000 pediatric hospitalizations and 4,500 deaths annually.¹ Symptoms of RSV are usually self-limiting in those individuals that are considered healthy and have normally developed respiratory systems. However, the risk of serious RSV illness is highest among pediatric patients with specific risk factors (i.e., prematurity, chronic lung disease, congenital heart disease, multiple congenital anomalies, and certain immunodeficiencies).² When RespiGam® (RSV-IGIV), the human immunoglobulin for RSV, was approved in 1996 for the prevention of RSV, it provided a much needed benefit for infants by preventing hospitalizations associated with RSV. However, RSV-IGIV has many disadvantages. It must be given by slow IV infusion, its supply is limited by lack of donors, and a child's immunizations must be carefully scheduled surrounding its administration.⁴ Synagis® (palivizumab), is a humanized monoclonal antibody (IgG1k) produced by recombinant DNA technology that binds to the F glycoprotein of RSV.³ It was approved for marketing by FDA in June 1998 and addresses the administration and safety concerns noted with RSV-IGIV.⁴

The IMPact-RSV Study Group demonstrated the safety and effectiveness of this monoclonal antibody.³ They reported a 55% reduction in hospitalizations in premature children and those with bronchopulmonary dysplasia, a form of chronic lung disease, as a result of prophylaxis for RSV with this agent. No significant differences were observed in reported adverse events between the study group and placebo. As a result of this study, the American Academy of Pediatrics (AAP) published guidelines for the use of palivizumab. Pediatric patients at high risk for RSV infection often require prophylaxis. These high-risk individuals are infants with a history of prematurity (≤ 36 weeks gestational age), infants with chronic lung disease (such as bronchopulmonary dysplasia) who require medical treatment, and infants with other co morbid serious medical conditions and/or environmental risk factors listed below.

Additional Risk Factors⁶

- Congenital heart defects - acyanotic
- Neurological disease with low birth weight
- More than 1 young sibling in the home
- Child care center attendance
- Exposure to tobacco smoke at home
- Anticipated cardiac surgery



Long distance from hospital care

RSV prophylaxis with palivizumab for two RSV seasons for those patients with less severe underlying disease is generally not recommended and should only be reserved for those patients with more severe chronic lung disease (i.e., those requiring medical therapy).

Palivizumab is dosed at 15 mg/kg every 28 days during the RSV season. While costs of a single 100 mg vial approximates \$1400, total cost for treatment may exceed \$5,000 per patient per season, therefore prior authorization is imperative to promote prudent prescribing of this agent.⁵

Setting & Population

Date Range of Analysis: TBD

Business Units Reviewed: TBD

Estimated Date of Mailing: TBD

Approval Criteria

- **Drug class for review:** Agents for RSV prophylaxis (palivizumab)
- **Age range:** Age < 2

Approval Criteria	
Treatment is being administered at the start or within the RSV season (based on geographical area).	Approved
< 2 years old with chronic lung disease that required treatment in the past 6 months.	Approved
Patients born <29 weeks of gestation and are currently ≤1 year of age.	Approved
Patients born between 29 and 32 weeks gestation and are currently ≤6 months of age.	Approved
Patients born between 33 and 35 weeks gestation *and are currently ≤6 months of age if they have one or more multiple risk factors present such as: congenital heart defects (acyanotic), neurological disease, low birth weight, more than 1 young sibling, child care center attendance, exposure to tobacco smoke, anticipated cardiac surgery, and/or long distance from hospital care.	Approved
*Weeks gestation calculated by completed weeks of gestation.	

Denial Criteria

- Agent is being used for second season prophylaxis unless the patient has chronic lung disease requiring medical therapy.

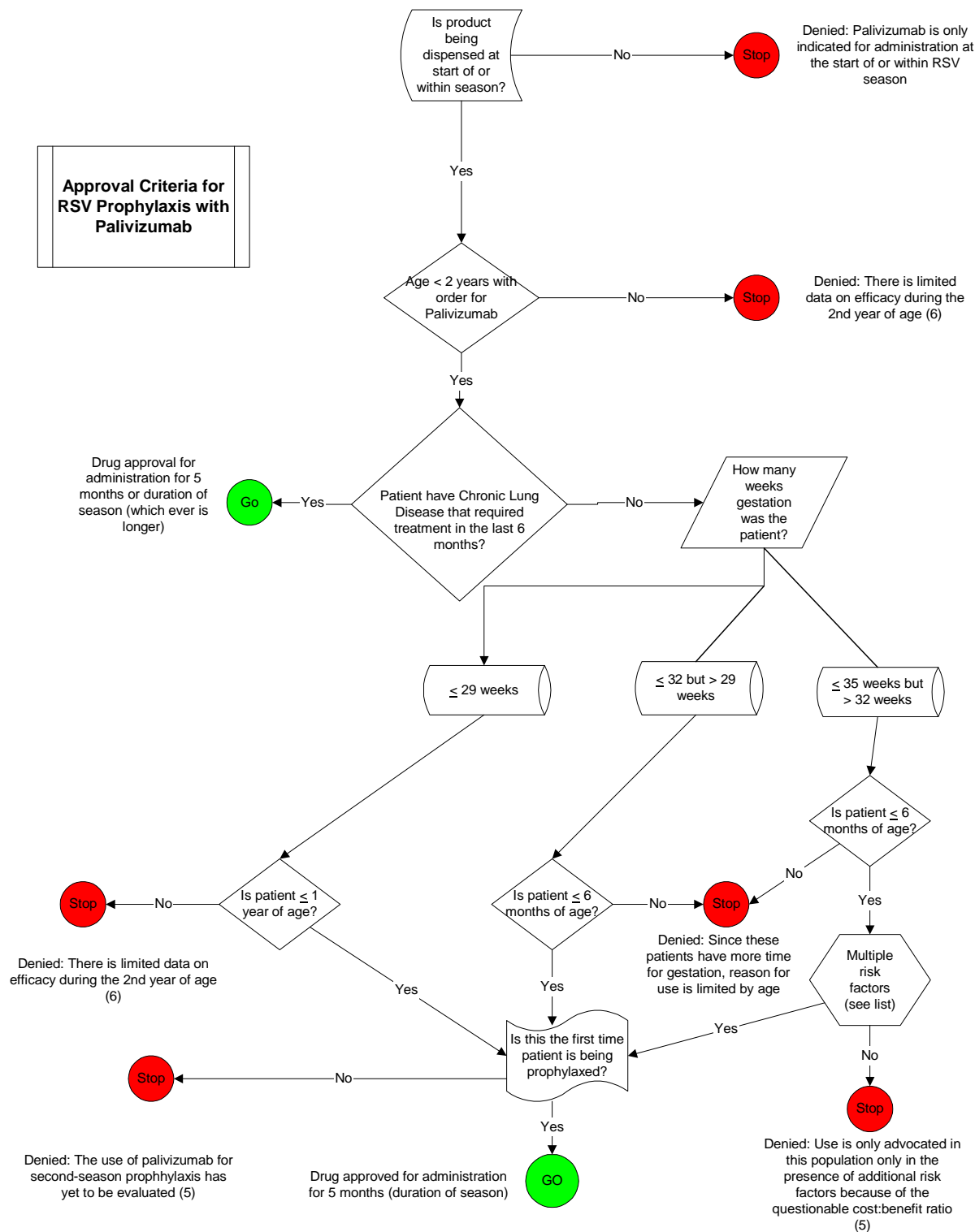
Required Documentation

Laboratory results:
MedWatch form:

Progress notes:
Other:



Flowchart of Criteria



References

1. Institute of Medicine Committee on Issues and Priorities for New Vaccine Development. Prospects for immunizing against respiratory syncytial virus. In: New Vaccine Development, Establishing Priorities. Washington, DC: National Academy of Sciences Press;1988;1:397-409.Synagis.
2. The IMPact-RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. *Pediatrics*. 1998;102:531-537.
3. Palivizumab for intramuscular administration. Gathersburg, MD: MedImmune, Inc; 12/99. Package Insert.
4. Nahata M,Robinson R. Respiratory syncytial virus (RSV) immune globulin and palivizumab for prevention of RSV infection. *Am J Health-Sys Pharm* 2000;(57):259-264.
5. Drug Topics Red Book 2002. Thomson Medical Economics. Synagis.
6. American Academy of Pediatrics Committee on ID and Comm on Fetus and Newborn-Prevention of RSV Infections: Indications for the use of palivizumab and update on the use of RSV-IGIV. *Pediatrics* 1998;102(5):1211-1215.

